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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------------------------|----------------------|-----------------------------|------------------|
| 10/555,301 | 02/01/2006 | Michael Andrew Jones | 4398-474 | 7804 |
| 23117 NIXON & VAN | 7590 03/31/200 NDERHYE. PC | EXAMINER | | |
| 901 NORTH GLEBE ROAD, 11TH FLOOR | | | BLIZZARD, CHRISTOPHER JAMES | |
| ARLINGTON, VA 22203 | | | ART UNIT | PAPER NUMBER |
| | | | 3771 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | |
|---|---|---|--|--|--|
| | 10/555,301 | JONES ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | CHRISTOPHER BLIZZARD | 3771 | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w. - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | lely filed the mailing date of this communication. (35 U.S.C. § 133). | | | |
| Status | | | | | |
| Responsive to communication(s) filed on <u>03/04</u> 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | | |
| Disposition of Claims | | | | | |
| 4) ☐ Claim(s) 54-66 is/are pending in the application 4a) Of the above claim(s) is/are withdrav 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 54-66 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examinet 10) ☐ The drawing(s) filed on 02 November 2005 is/are Applicant may not request that any objection to the contraction. | vn from consideration. relection requirement. r. re: a) □ accepted or b) ☒ object drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/4/09 3/7/07 11/2/05. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ite | | | |

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DETAILED ACTION

Introduction

1. This Office Action is in response to amendment filed on March, 4, 2009. As directed by amendment, claims 1-53 were cancelled and claims 54-66 were added. Thus, claims 54-66 are currently pending in this application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "decoupling structure" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly

claiming the subject matter which the applicant regards as his invention.

- 4. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "decoupling structure" in claim 54 is used by the claim to mean "flexible coupling", while the accepted meaning is "selectively separable connection." The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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- 7. Claims 54-58, 60, 61, and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by McCall (5,921,239).
- 8. Regarding claims 54, 55, 56, 57, 58, 60 and 61, McCall et al. discloses a mask system (10) comprising a shell (14) made of flexible material (column 5, lines 15-16) and includes a decoupling structure (column 5, lines 44-51), a cushion (12) provided to the shell to form a seal with the patient (column 3, lines 37-39), and an approximately 90 degrees elbow conduit portion (16) (fig. 1) having a first end provided to the shell (42) and being associated with the decoupling structure (fig. 8) and a second swivel end (43) adapted to engage an air delivery conduit (18), whereby any movement of the air delivery conduit creating drag forces applied to the conduit portion can be decoupled from the cushion so as to avoid disruption of the seal (column 3, lines 37-39).
- 9. Regarding claims 64-66, McCall et al. further discloses a frame (20) to support the shell (14) made of a relatively hard material (column 4, lines 5-11) compared to the shell, and includes a headgear (21) connection point (65).
- 10. Claims 54-56 and 58-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Sullivan (6,039,044).

Regarding claims 54-56 and 58-62, Sullivan discloses a mask system (fig. 2) comprising a flexible shell (13) (column 3, lines 62-63) having section that is a flexible decoupling structure (20) including a bellows portion (column 2, lines 43-49), a cushion (15) provided to the shell to form a seal with the patient (column 4, lines 1-4), and an approximately 90 degree elbow conduit portion (24) (fig. 2) having two vent orifices (25), a first end (fig. 2, near 21) associated with the decoupling structure (20) and a second

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end (fig. 2, near 23) adapted to engage an air delivery conduit (23), whereby any movement of the air delivery conduit creating drag forces applied to the conduit portion can be decoupled from the cushion so as to avoid disruption of the seal (column 4, lines 33-38).

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (6,039,044) in views of Scarberry (6,397,847).
- 13. Regarding claim 63, Sullivan does no disclose reinforcing ribs. Scarberry et al. teaches a mask system (10) with reinforcing ribs (42) provided to a shell (27) in a region surrounding an aperture (30) of the shell (27) where the conduit portion (12) is provided (fig. 3). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mask system of Sullivan with reinforcing ribs as taught by Scarberry in order to provide the advantage of providing uniform compression of the cushion when in contact with the patient's face, as taught by Scarberry (column 9, lines 46-49).
- 14. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCall (5,921,239) in views of Scarberry (6,397,847).

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15. Regarding claim 63, McCall et al. does no disclose reinforcing ribs. Scarberry et al. teaches a mask system (10) with reinforcing ribs (42) provided to a shell (27) in a region surrounding an aperture (30) of the shell (27) where the conduit portion (12) is provided (fig. 3). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mask system of McCall et al. with reinforcing ribs as taught by Scarberry in order to provide the advantage of providing uniform compression of the cushion when in contact with the patient's face, as taught by Scarberry (column 9, lines 46-49).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dennis (6,851,428) a mask system with mask folds and a ball and swivel joint, Biener (2003/0221691) a mask with a decoupling structure, and Frater (2004/0144386) a mask with gusset.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/ Examiner, Art Unit 3771

/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771